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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/048,165   | 01/29/2002  | Martin Caldwell      | 741890-0023         | 4375             |
| 22204  | 7590        | 06/10/2004           | EXAMINER            |                  |
| NIXON PEABODY, LLP<br>401 9TH STREET, NW<br>SUITE 900<br>WASHINGTON, DC 20004-2128 |             |                      | PANTUCK, BRADFORD C |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                |                  |

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/048,165

**Applicant(s)**

CALDWELL ET AL.

**Examiner**

Bradford C Pantuck

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 15, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 29, 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-15-2002.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 27-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 15, 2004.

### *Drawings*

2. The drawings are objected to because Figure 6 is inconsistent with the progression from Fig. 3 to Fig. 4 to Fig. 5. Internal wall 3 is on the top and external wall 4 is on the bottom of each figure, except for Fig. 6. This makes it unclear whether the puncture is made from the inside or the outside. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

3. The disclosure is objected to because of the following informalities: In the last paragraph on page 10, Applicant explains, with reference to figures 1-8:

“The invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is directed away from the patient's body during insertion. This is achieved in a way that ensures that the cannula is automatically drawn into position.”

However, in drawings 3-5, the point of the trocar is shown directed towards the patient's body. The trocar is shown breaking through the exterior surface and then the interior surface of the flesh. Therefore, the specification is contradicting the corresponding drawings.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

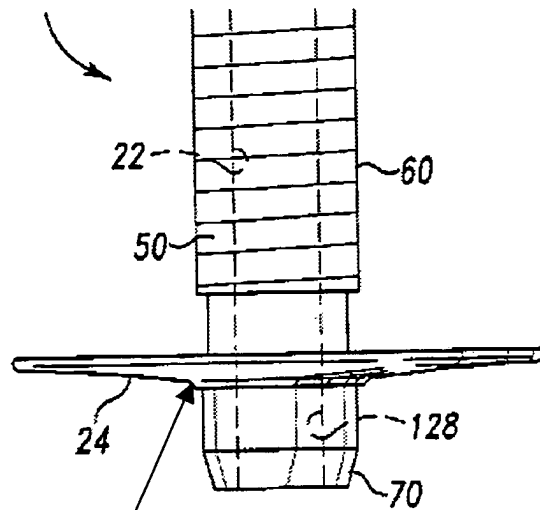
4. Claims 1, 3-7, 9-13, 15-20, and 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,051 B1 to Moenning et al. Regarding Claim 1, Moenning discloses a surgical device including a cannula (14) [Fig. 4], a trocar (16) carried on the inner surface of the cannula [Fig. 3], and a fixing means (24 and 52) to lock the cannula in position on the patient's body during surgery [Column 11, lines 3-11]. The trocar is removably mounted on the cannula, and while the trocar is mounted on the cannula, the whole device does not allow air to pass through the puncture wound in the body [Column 9, lines 32-38; Column 12, lines 1-5]. Although, it is not explicitly stated that the trocar is within the cannula while the cavity is insufflated, Moenning does state that other instruments can be inserted through cannula (14), while maintaining a fluid-tight seal [Column 11, lines 31-37].

Therefore, one must assume that the trocar could be reinserted within the cannula (14) and the seal could be maintained.

The device is capable of having a trocar inserted through it from the exterior [as shown in Fig. 3] or from the interior of the patient. Examiner notes that Applicant does not explain in detail how Applicant's device can be inserted from the interior of the patient beyond "through an access port." Regardless, Moenning's device is equally capable of performing such a seemingly difficult intended use as it contains all of the claimed structure of the Applicant's device.

5. Regarding Claim 3, Moenning's device has a trocar with a cutting edge, which facilitates cutting the body cavity wall [Fig. 3].
6. Regarding Claims 4 and 5, Moenning's Figure 1 shows a trocar (16) with several different shoulders. The proximal-most portion of the trocar has a handle for the surgeon to hold: this handle can be considered a guide.
7. Regarding Claims 6 and 7, Moenning's device has a means (24) for releasably attaching to the interior of the body. The means is a distal ring.
8. Regarding Claim 9, Moenning's sealing member in combination with the rest of his device acts as a valve, as when cannula 14 is removed from component (20) allows air to pass through the device [Column 12, lines 1-4].
9. Regarding Claim 10, ring (52) is a part of the fixing means [Figure 5]. Such a ring would prevent distal movement of the device.
10. Regarding Claim 11, the anchor ring (52) incorporates a thread for engaging a complementary thread on component (60), as shown in Figure 2B.

11. Regarding Claims 12 and 25, the anchor ring itself acts as a valve, determining when air is contained or released. A valve is merely a mechanism that regulates the flow of gases, by closing or opening. The anchor ring (52) can be rotated or tilted to either allow or disallow the passage of gas from the insufflated body.
12. Regarding Claim 13, Moenning's invention has an external seal (top [proximal] surface of component 24) and an internal valve (bottom [distal] surface of component 52) [see Fig. 6], which are respectively mounted on opposite ends of the cannula.
13. Regarding Claim 15, Moenning's device has a means (threads 50) for allowing seal (24) to connect and be tightened onto valve (52).
14. Regarding Claim 16, a diaphragm is a thin disc that divides or separates. Moenning's component (24) acts a diaphragm seal in that it is a thin disc that can act as a valve.
15. Regarding Claim 17, the seal ("seal housing") 24 has an extended entry port, which is the central hole in the middle of the disc 24. As is evident from Fig. 2B, the hole extends down distally, having a lip extending from the disc.
16. Regarding Claim 18, the entry port (central hole in seal 24) has a conical section, as is evident in the below drawing:



**Fig. 2B**

Conical  
flange

17. Regarding Claim 19, both the distal and proximal ends of the cannula (14) are ports, which the user can pump air through in order to inflate the body.
18. Regarding Claim 20, the proximal end of cannula (14) is an insufflation port, which communicates with the lumen of the cannula, which can be called the "insufflation lumen." The distal end of the cannula (14) can be called a duct and it communicates with the body.
19. Regarding Claim 22, Moenning's anchor ring (52) has all of the structure of Applicant's anchor ring (7) as shown in Figure 2. It is unclear where in the drawings any cushioning means is shown incorporated into anchor ring (7).

20. Regarding Claim 23, distal ring (24) *acts* as a cushion means, being a disc with quite a large diameter, which will spread out the force that it puts on the body (34) and will ensure a gas-tight seal.
21. Regarding Claim 24, the proximal handle portion of the device as shown in Figure 4 will allow the user to hold onto the device, preventing it from falling into the body cavity.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,658,306 to Kieturakis et al. Kieturakis discloses a method of inserting a surgical device into an inflated abdomen [Column 14, lines 32-38] through an access port (91) [Column 5, lines 37-45]. Kieturakis' device has a cannula (22), a trocar (knife 28) carried on the distal end of the cannula, and two fixing means (96 and 107), which are able to anchor the cannula in position [Fig. 11; Column 6, lines 16-22]. In the previously mentioned passage, Kieturakis describes a method of inserting the trocar through the access port (91) into the body, cutting tissue outwardly from within the body cavity with the trocar (28) and inserting the cannula (22) into the incision (106).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person



having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,451,051 B1 to Moenning et al. in view of U.S. Patent No. 4,601,710 to Moll. Moenning discloses a trocar (16) removably mounted on cannula (14), but does not disclose using engageable short threads for this purpose. Moenning's trocar (16) and cannula (14) are merely slideably mounted on each other. However, Moll discloses a trocar (84/106) removeably mounted on cannula (82) with threads [Column 4, lines 35-44; Fig. 10]. Implicitly, threads such as these more securely fasten two components. Moll teaches that threads such as these would allow the trocar to be connected to the cannula removeably so that the user could detach a blunt trocar for sharpening. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to fasten a trocar to a cannula with engageable short threads, as taught by Moll, in order to *securely* but *removeably* attach them to each other.
24. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,451,051 B1 to Moenning et al. Moenning's distal ring (24) and cannula (14) are separate members. However, it would be obvious to make them one integrally formed single unit, because it has been held that "integrally" is sufficiently broad to embrace construction united by such means as fastening and welding, as disclosed in Moenning's disclosure.
25. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,451,051 B1 to Moenning et al. Moenning's seal (24) and valve (52) are

separate members. However, it would be obvious to make them one integrally formed single unit, because it has been held that “integrally” is sufficiently broad to embrace construction united by such means as fastening and welding, as disclosed in Moenning’s disclosure.

***Allowable Subject Matter***

26. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,634,937 A to Mollenauer et al.

U.S. Patent No. 5,562,688 to Riza

U.S. Patent No. 5,534,009 to Jack

U.S. Patent No. 5,405,328 to Vidal et al.

U.S. Patent No. 6,544,277 B1 to O’Heeron et al.

U.S. Patent No. 5,330,497 A to Freitas et al.

U.S. Patent No. 6,689,147 B1 to Koster

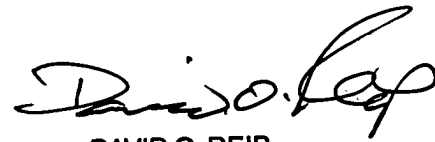
U.S. Patent No. 5,810,863 to Wolf et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BCP*  
BCP  
June 4, 2004

  
DAVID O. REIP  
PRIMARY EXAMINER